

CORRES. CONTROL
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BENEDETTI, R.L.		
BENJAMIN, A.		
BERMAN, H.S.		
CARNIVAL, G.J.		
COPP, R.D.		
CORDOVA, R.C.		
DAVIS, J.G.		
FERRERA, D.W.		
FRANZ, W.A.		
HANNI, B.J.		
HEALY, T.J.		
HEDAH, T.G.		
HILBIG, J.G.		
HUTCHINS, N.M.		
KIRBY, W.A.		
KUESTER, A.W.		
MAHAFFEY, J.W.		
MANN, H.P.		
MARX, G.E.		
McKENNA, F.G.	XX	
MORGAN, R.V.		
PIZZUTO, V.M.		
POTTER, G.L.		
SANDLIN, N.B.		
SATTERWHITE, D.G.		
SCHUBERT, A.L.		
SETLOCK, G.H.		
SULLIVAN, M.T.		
SWANSON, E.R.		
WILKINSON, R.B.		
WILSON, J.M.		

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Reviewed for Addressee
Corres. Control RFP

1-27-94
DATE BY

Ref Ltr. #

DOE ORDER # 5400.5

RF-46522 (Rev. 9/93)

Department of Energy

ROCKY FLATS OFFICE
P.O. BOX 928
GOLDEN, COLORADO 80402-0928

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Mr. Robert Duprey, Director
Hazardous Waste Management Division
U.S. Environmental Protection Agency, Region VIII
999 18th Street, Suite 500
Denver, CO 80202-2405

Ms. Joan Sowinski, Manager
Hazardous Waste Control Program
Colorado Department of Health
4300 Cherry Creek Drive South
Denver, CO 80222-1530

Dear Mr. Duprey and Ms. Sowinski:

This is to acknowledge receipt of your letter dated January 11, 1994 which addressed data aggregation for the purpose of conducting the human health exposure assessment. This letter also transmits (1) proposed changes to the risk assessment methodology in your January 11, 1994 letter and (2) our understanding of the criteria for resumption of the regulatory milestone clock. At this point, we do not concur with the methodology enclosed in your January 11, 1994 letter.

Enclosed are our proposed changes to your January 11, 1994 assessment methodology. We believe the guidelines as they currently stand will require unnecessary duplication of assessments. In cases where it is necessary to subdivide the source, we prefer to use a single, conservative assessment to calculate exposure. In this way, we can produce the most useful (i.e., a conservative) assessment aid to us in making cleanup decisions. Duplicating assessments seems to add unnecessary expense and delay to the cleanup process. In addition, your definition of "hot spots" is different than that in our internal guidelines and requirements (DOE Order 5400.5, Radiation Protection of the Public and the Environment) which may cause confusion.

These proposed changes were discussed at a January 18, 1994 meeting between DOE/RFO, the U.S. Environmental Protection Agency, Region VIII, (EPA) and the Colorado Department of Health (CDH). The changes were faxed to your offices on January 19, 1994 and no response was provided.

In accordance with your August 12, 1994 letter, we understood at the time of the stop work order that EPA and CDH would seek input from DOE/RFO prior to deciding on a methodology. We believe that this approach is sound, because it gives all parties to the Interagency Agreement an opportunity to discuss and understand environmental regulatory policy, increasing the effectiveness of the cleanup process at the RFP. However, we do not feel we have been brought into the discussions in a timely manner up



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to this point. Your January 11, 1994 letter was formally issued to us before a DOE/RFO, EPA, and CDH meeting was convened to discuss your proposed methodology.

It is our belief that the root cause of the stop work order for baseline risk assessment contained in your August 12, 1993 letter lies in differences between the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), and the Colorado Hazardous Waste Act (CHWA) as well as variations in the interpretations of the statutes and implementing regulations by EPA and CDH.

It was not clear from the January 11, 1994 letter how you are interpreting the regulatory milestone clock. It is our understanding that the milestone clock will not resume until DOE, EPA, and CDH all agree on a human health exposure assessment methodology. If the milestone clock has started without DOE being allowed to comment or agree on the methodology, you may consider this letter a notice for proceeding with dispute resolution, pursuant to Parts 12 and 16 of the Interagency Agreement.

These issues must be resolved quickly. In order to accomplish this, I suggest that a meeting be held in the near future to discuss how the cleanup may be resumed without delay.

Sincerely,



Martin H. McBride
Acting Assistant Manager
for Environmental Restoration

Enclosure

cc:
M. Silverman, OOM, RFO
A. Pauole, OOM, RFO
A. Rampertaap, EM-453, HQ
R. Schassburger, DAMER, RFO
M. Roy, OCC, RFO
S. Olinger, AMES&H, RFO
B. Thatcher, ER, RFO
S. Stiger, EG&G
M. Hestmark, EPA

The U.S. Department of Energy, Rocky Flats Office (DOE/RFO) has reviewed the data aggregation methodology attached to the U.S. Environmental Protection Agency, Region VIII, (EPA) and Colorado Department of Health's January 11, 1994 letter to DOE/RFO regarding the lifting of the stop work order. Our primary concerns are as follows:

- 1) two source risk assessments will be required for identical sources,
- 2) residential exposure units do not represent the RME for all of the OUs (i.e., the industrial area OUs), and
- 3) the definition of a hot spot conflicts with DOE Order 5400.5, Radiation Protection of the Public and the Environment, and only direct contact exposures pathways are to be considered for hot spots.

We propose that two risk assessments be performed:

- 1) source risk assessment
- 2) hot spot risk assessment

The source risk assessment would fall into one of three categories described as follows:

- 1) source area defined by the background arithmetic mean plus two standard deviations. Assuming that data within the source approximate a normal distribution, the UCL would be calculated using an arithmetic mean and standard deviation as described in Highlight 6 of EPA's "Supplemental Guidance to RAGS: Calculating the Concentration Term".
- 2) source area defined by the background arithmetic mean plus two standard deviations. Assuming that data within the source approximate a lognormal distribution, the UCL would be calculated using the arithmetic mean and standard deviation as described in Highlight 5 of EPA's "Supplemental Guidance to RAGS: Calculating the Concentration Term". However, if the calculated UCL exceeds the maximum concentration identified within the source, the maximum value will be used in lieu of the UCL.
- 3) source area defined by the background arithmetic mean plus two standard deviations; however, cannot assume that data within the source approximate either a normal or lognormal distribution. In this case, the source area will be redefined based on further analysis of the data (see the attachment).

The details of the data aggregation process for sources are contained in the attachment entitled "Statistical Approach for Data Aggregation".

We propose that the definition for hot spots be consistent with that in DOE Order 5400.5, which applies to radionuclides. However, we propose that this definition also be adopted for other COCs to provide consistency. Consideration of only direct contact exposures for hot spots is consistent with RAGS. Finally, we propose that a hot spot be confined to an area of less than 25 square meters (per DOE Order 5400.5) and have a concentration exceeding 100*RBC (risk of approximately 1 EE-4). Finally, we propose that that hot spot risk assessment be kept separate from the source risk assessment which is also consistent with RAGS.

STATISTICAL APPROACH FOR DATA AGGREGATION

The following discussion presents an approach that defines source areas and provides for a defensible statistical approach to data aggregation. The overall approach relies on the fact that data collected over some finite region, from a given media, can be evaluated statistically to determine the appropriate spatial and temporal distributions. Given the fact that a source area is defined as that area where the contaminants are found to be at concentrations above background. Where above background is defined as that value which exceeds the calculated mean from a representative background population, plus two times the standard deviation. Given this definition of a source area there are several questions that must be considered. These are the determination of whether: 1) all of the data points found to be at above background concentrations are from the same population, 2) all of the data points are independent, and 3) any external factors that may affect the data are both uniform and small.

Provided that all of the basic assumptions are satisfied then the following procedural steps are to be followed when reviewing the data.

STEP 1: EXPLORATORY DATA ANALYSIS

This step of the statistical analysis is fundamental to determining the concentration of the contaminant. This step includes data posting or plotting the actual data as concentration versus x - y position. This will aid in determining the above background locations as well as the potential for multiple source areas. In addition to data posting normal and log-normal probability plots are made along with the data plotted in a histogram which presents the data with respect to the frequency of detection and the magnitude of the contaminant. A histogram will yield information as to the potential for single or multiple populations. The data posting, probability plots, and the histogram are followed by a set of summary statistics which include the mean, median, standard deviation, variance, and the coefficient of variation at a minimum. The sum of the above mentioned exploratory evaluations will provide a defensible basis for making decisions regarding the aggregation of data and the calculation of the concentration term used in risk assessment.

STEP 2: TESTING FOR NORMALITY ON NORMAL AND LOG-TRANSFORMED DATA

Data found to be above background concentrations must be evaluated statistically to determine the distribution. A number of tests can be used including the Shapiro-Wilk Test (on both raw and log-transformed data), probability plot-correlation coefficient, probability plots, and in certain circumstances the coefficient of variation is also applicable (these tests can be found in most computer based statistical analysis packages or are taken from standard statistical references or USEPA Guidance). The test that will be used as a default will be the Shapiro-Wilk Test. This test will be used exclusively unless the conditions of the data indicate that the application of this test is inappropriate. The type of distribution can greatly affect the statistical tools that can be applied in the evaluation of sampling data. To be able to apply standard parametric analysis techniques the data must be normally distributed (includes data that has been log-transformed or hence log-normal). When data is not normally distributed or can not be transformed then non-parametric analysis techniques must be used.

STEP 3: EVALUATING THE VARIABILITY OF DATA

Once a determination of normality (or non-normality) has been made and the data is found to be significantly non-normal then the data is evaluated based on the exploratory

analysis to ascertain the potential for multiple populations. Provided the data posting histogram and summary statistics indicates that there is a clustering of significantly higher values which would represent a separate population the subsets of the data will be tested. The techniques often used to test the multiple populations include parametric and non-parametric techniques. The original data set will be segregated into separate populations which will represent a potential primary and secondary source. Each of these subsets will be evaluated to determine the appropriateness of the groupings.

In many cases high variability among data points indicates that the data may actually represent several different populations. The tests performed are to ensure that the segregation of the data is supported with the appropriate statistical analysis. Methods can be employed to evaluate the potential that several data points are actually from a different population. Once several data points (clustered in space or time) have been identified as potentially representing a different population the use of ANOVA (parametric or non-parametric as appropriate) is used to determine whether the differences in the means of the two populations is statistically significant. An additional evaluation will be made to ensure that the two populations are not only statistically different but also differ in terms of relative magnitude from a risk assessment standpoint. This difference is anticipated to be an order of magnitude or greater to ensure that the risk evaluation can provide useful information.

The techniques that are used may be parametric techniques while others are non-parametric methods. The central difference between parametric and non-parametric is in the fact that parametric analysis utilizes estimates of the mean to differentiate between groups while non-parametric techniques use the median of the data. For this reason parametric techniques are considered to be more powerful than non-parametric, when the data is normally distributed or can be appropriately transformed. Obviously if the data is not normal then the non-parametric techniques are more powerful in determining differences among groups of data.

The result of the evaluation of the two subsets of the original population will usually indicate statistically significant differences. The residues and their differences are found which are used to evaluate the statistical significance for each data point in the suspected population to verify the specific points that are producing the difference in the means. These tests are used to segregate those data points which are likely part of a separate and distinct population.

STEP 4: AGGREGATING THE DATA FOR EACH POPULATION (This assumes that the data set for the original source area as defined from the comparison to background exhibits variability in the data sufficient to justify two separate populations and defended using statistical analysis)

Once the determination has been made that there are indeed two separate populations, which is considered to be a rare event rather than the norm, then the data must be evaluated as to the physical constraints (topography, hydrogeology, atmospheric conditions, release and transport mechanisms, etc.). This evaluation should consider the spatial distribution of the data points with respect to the likelihood that the data points could have resulted from non-random or non-uniform mechanisms. This evaluation is required to take into consideration the possibility of localized spills, or leaks, rather than wide spread contamination. This evaluation is essentially in terms of differentiating localized areas of contamination as opposed to uniform contamination since the goal of the risk assessment is to characterize average exposures over a lifetime rather than maximum exposures over short time periods (see Supplemental Guidance to RAGS: Calculating the Concentration Term).

Once the appropriate physical evaluation has been complete the next step is to relate the separate populations to specific regions, consistent with the physical properties of the site. This spatial orientation of the data then is used to develop separate source terms for evaluating risk. In the event that the data is found to represent separate populations and the data points are clustered in space and time and the two (or more) populations are subsets of the original domain then the methods outlined in the Supplemental Guidance to RAGS: Calculating the Concentration Term are used to determine the appropriate 95% UCLs for the different populations. The distinct UCLs are then used to evaluate risk based on the appropriate exposure scenario and hence unit.

The separate UCLs will represent separate source areas within the geographical region characterized. These different source areas will be evaluated to determine the most appropriate with respect to evaluating the risk for the specified exposure scenario. In the event that the two or more populations exhibit significantly different UCLs for the same COC then the source area with the greatest UCL will be used in the exposure assessment and an assessment of the effects of environmental transport will be performed to ensure that the potential for contaminant accumulation is not overlooked. The primary risk evaluation will be made on the source area with the highest UCL as long as the spatial extent of the contaminated region is greater than or equal to the size of the appropriate exposure unit (separate consideration would be given to ecological receptors and the exposure unit size).

HOT SPOT EVALUATION:

The average concentration is used for the source term: 1) carcinogenic and chronic non-carcinogenic toxicity criteria are based on lifetime average exposures; and 2) average concentration is most representative of the concentrations that would be contacted at a site over time. This information was taken directly from the Supplemental Guidance to RAGS: Calculating the Concentration Term.

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DISCUSSION OF FIGURE 1

Figure 1 is an illustration of the potential for significant variability of data in the original source area.

The large area has a total of 23 data points which when tested against background were found to be statistically significant. These 23 locations and the associated concentrations for a particular contaminant were then considered to be the "source" area. Once the "source" area was defined the procedures for calculating the concentration term are followed as modified in this proposal. The total data set of 23 points is tested for normality (or more appropriately log-normal distribution). In this particular case the probability plot was found to exhibit significant non-linearity (condition for non-normal data). The next step was to determine the significant contributors to the non-normal conditions. This is accomplished by testing for outliers and then using these results as a separate population and performing a non-parametric ANOVA or other appropriate test for differences in means, medians, or variance. This determination resulted in the identification of six data points which when combined together exhibited near normal, when the data was appropriately transformed, conditions and the remaining 17 data points also exhibited normality. The ANOVA performed to test the difference in the means of these two populations showed results that indicated the means were significantly different and hence were probably two different populations.

It is important to note that the appropriate statistical tests (normality) need to be performed on the subset of the original data to ensure that the most significant contributors to non-normality are identified.

It is also important to note that in this example the small subset of the original data (comprised of 6 data points) was clustered together both spatially and temporally. Also for the purposes of this example the small subset of the original data are significantly greater in concentration than the remaining data points, which resulted in the determination that the data set actually contained two separate populations. The difference cannot be stated as a definite multiplier, however the expected difference in the means would be an order of magnitude or more otherwise the statistical analysis would not have indicated different populations.

The overall process is described generally in steps 1 through 4 in the Statistical Approach Document. the discussion above illustrates how the procedure would apply to the assumed data set.

FIGURE 1: ILLUSTRATION OF SOURCE AREAS
AND STATISTICAL APPROACH

